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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,124	03/26/2001	Yasuo Nagasawa	4001-0001C	8886

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EXAMINER
MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
1636	12

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/816,124	Applicant(s) NAGASAWA ET AL.	
	Examiner Terry A. McKelvey	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-11,14-19 and 21-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/308,164* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The computer readable form of the sequence listing was entered into the file, but contained the following errors which were corrected: non-ASCII "garbage" was deleted at the beginning and/or end of files.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants should carefully review the specification to identify and properly label each sequence that is referred to within the specification, including those contained in drawings. Sequences in drawings can be identified with a SEQ ID NO: in the Brief Description of the Drawings for the figure or be present in the figure itself. If one or more sequences are referred to in the specification that are not present in the Sequence Listing, then a new Sequence Listing, a new CRF diskette containing the Sequence Listing and a new statement that the two are the same

and includes no new matter must be submitted in order to fully comply with the Sequence Rules.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. Any response to this Office Action which fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Election/Restrictions

Applicant's election without traverse of Group III, claims 12-13 and 20 in Paper No. 11, filed 7/30/02 is acknowledged.

Claims 1-11, 14-19, and 21-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Objections

Claims 12-13 are objected to because of the following informalities: they depend on non-elected claims. The claims need to be amended to no longer depend on non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-13 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 12-13, there is no positive antecedent basis for "the cells of claim (6 or 7)" because claim (6 and 7) recite only "a cell".

Regarding claims 12-13 and 20, the claims are missing "and" between step (b) and last step (c) and thus it is unclear whether all of the steps are included (and no more than those steps).

Regarding claim 20, there is no positive antecedent basis for "the reporter gene product". Amending the claim to recite "the product of the reporter gene" would be remedial.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered

therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark et al (applicant reference AA) in view of Beach et al (U.S. Patent No. 6,025,192).

Stark et al teach cell lines transfected with constructs (vectors) which express a reporter compound under the control of a regulatory region (such as an interferon-inducible regulatory region) inducible directly or indirectly by a stimulating substance (which causes cytokine production or utilization). This reference teaches that the reporter compound can be luciferase, CAT, beta-glucuronidase, or a number of other genes for which detection systems are available or cytotoxic and expression of the compound is indicated by the death of the cells, such as HGPRT when 6-thioguanine is used in a HPRT- cell line. Stark et al teach a method of using the cell lines transfected with the constructs comprising exposing the cells to a test compound, stimulating the reporter gene construct under the control of the regulatory region, and testing whether the

cells die or not (for cytotoxic reporters) or detecting the activity of the reporter (for non-cytotoxic reporters). This reference also teaches assaying genes for inhibitory effects for the assay comprising introducing the genes into test cells (pages 44-46). It is taught that introducing test compounds in the assay method taught by the reference will vary with the test compound (page 47). The method is taught as being useful for determining whether a test compound is potentially useful for administration to a mammal for antiviral therapy (pages 1-11).

Stark et al do not specifically teach introducing a gene library into the assay system as the test compounds and isolating the gene identified by the screening method step.

Beach et al teach retroviral vectors and libraries of vectors which express different genes, for use in elucidation of mammalian gene function (abstract) and identification and isolation of nucleic acid sequences which inhibit the function of a mammalian gene (column 2). It is taught that the method for identifying a nucleic acid sequence which inhibits the function of a mammalian gene, in this instance, comprises: infecting a mammalian cell expressing a selectable marker with a retroviral vector containing a nucleic acid sequence derived from the gene of interest wherein upon infection the nucleic acid sequence is expressed, selecting for the selectable marker, and assaying for the selectable marker, so if the selectable marker is inhibited, a nucleic acid sequence which inhibits the

function of the mammalian gene is identified (column 13). Beach et al teach that the present invention includes construction of cDNA libraries that may be utilized in the assay described above (column 14). This reference also teaches that growth regulatory cytokines may be identified (or survival factors that suppress cell death) by expression of cDNA libraries directly in the target cells (column 17, lines 39-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to alter the assay method taught by Stark et al by using a gene library as the test compounds and isolate the genes identified by the assay because Stark et al teach that it is within the ordinary skill in the art to use vectors in which a gene capable of causing cell death is operably linked to a regulatory region (such as an interferon-inducible regulatory region, which is stimulated extracellularly) in an assay to identify test compounds that interfere with that stimulation by screening for altered expression of the selectable marker, that genes can be assayed for inhibitory effects, and that introducing test compounds in the assay method will vary with the test compound, and Beach et al teach that it is within the ordinary skill in the art to identify and isolate a nucleic acid sequence which inhibits the function of a mammalian gene by infecting a gene library in a cell expressing a selectable marker, selecting for the

selectable marker, and identifying and isolating the gene which inhibits the function of the mammalian gene.

One would have been motivated to do so for the expected benefit of identifying genes that encode compounds that are potentially useful therapeutically as taught by Stark et al, and for use in elucidation of mammalian gene function and identification of inhibitory genes as taught by Beach et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success in practicing the claimed invention.

Regarding the use of host cells that cannot produce HGPRT, the use of HGPRT as the selectable marker gene, and use of 6-thioguanine in the assay method, it would have been obvious to do so because Stark et al specifically teach these components as a selectable marker screening system to be used in the method.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original

signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning missing attachments or other minor formalities of this communication should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

October 18, 2002

Application No.: 09/816,124

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The application sets forth sequences without identifiers; for example: Figures 2, 3, 6, etc + throughout the specification. Some of these sequences appear to be absent from the Sequence listings.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE